

REMARKS

The present communication is responsive to the Office Action mailed November 1, 2007. A Petition for a three-month extension of the term for response to said Office Action, to and including May 1, 2007, is transmitted herewith.

Claims 1-9, and 11-41 remain pending in the present application. Claims 10, and 42-43 remain cancelled without prejudice. Claims 1, 11, 21, and 31 have been amended in the current response. No new matter has been added. Support for the claim amendments can be found in the disclosure as originally filed.

The objection by the Examiner to the recitation that the "central region of the contact element being *unencumbered* by the coating" in claim 11 is rendered moot by the Applicants deletion of this recitation in the claim.

In the present Office Action, the Examiner rejected claims 1 and 9 under 35 U.S.C. § 102(b) as begin anticipated by U.S. Patent No. 5,989,291 to *Ralph et al.* ("*Ralph*"). The Examiner asserts that *Ralph* discloses an artificial intervertebral disc implant with first and second baseplates 100a, 100b with outward surfaces extending down and upward respectively that have grooves in a side surface with a vertebral contact element 120 secured thereto. The Examiner further asserts that it can be seen that the central portion of the contact element 120 is remote from the outside surfaces so as to form a gap in the central area.

The vertebral contact element 120 to which the Examiner asserts is shown in *Ralph* is actually a circumferential wall 120 which "is resilient and which is provided to prevent vessels and tissues from entering within the interior of the device." See col.6, 11.15-17. In *Ralph*, the circumferential wall 120 is not designed to contact a vertebral body, but rather

simply hold the baseplates together and prevent any tissue ingrowth into the moveable structure of *Ralph*.

Applicants respectfully assert that amended independent claim 1 is unanticipated by *Ralph* because the cited reference neither teaches nor suggests an artificial intervertebral disc including "a vertebral body contact element adapted to engage a vertebral endplate." This claim amendment is supported by the originally filed specification in at least paragraphs [0027]-[0028]. Applicants therefore respectfully request reconsideration and allowance of the claims over *Ralph*.

Further, the Examiner has rejected claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,370,697 to *Baumgartner* ("*Baumgartner*") in view of U.S. Patent No. 4,759,769 to *Hedman et al.* ("*Hedman*"). The Examiner asserts that FIG. 5 of *Baumgartner* shows a vertebral contact element 44 having a resting shape of a dome convexly extending from orthopedic device 2. The Examiner further asserts that *Baumgartner* discloses that the contact element is a wire mesh. However, the Examiner acknowledges that *Baumgartner* fails to disclose the outer surface of a baseplate having a groove. The Examiner contends that *Hedman* does teach a groove structure and asserts that it would have been obvious to combine *Hedman* with *Baumgartner* to render independent claim 1, as well as its dependent claims, obvious and unpatentable.

In response to Applicants' arguments presented in the August 14, 2006 response, the Examiner asserts that because *Hedman* teaches that grooves can be provided in a surface to retain a compressible member at a location, *Baumgartner* may be modified to incorporate a groove in an outward surface to retain the mesh thereon. *Hedman* discloses an artificial spinal disc having a front disc 20, having upper and lower member 26 and 28. The interior surfaces of the upper and lower members include

recesses 34 and 52 for receiving springs therein. The recesses 34 and 52 face one another and are disposed on the interior surface of the respective upper and lower members. The recesses help the pivoting or hingedly connected action of the members during compression and extension. As included in claim 1, the groove is disposed in at least one of the outwardly facing surfaces of the baseplates. This is clearly not shown or suggested by *Hedman*, which discloses inwardly facing recesses 34 and 52. Further, springs 72 are seated within recesses on either of the *inside surfaces* of a respective baseplate and not on the *outwardly-facing surface* of a baseplate as recited in claim 1 of the present application. In fact, *Hedman* teaches away from a baseplate having an exterior surface that includes a groove. See col.2, ll.49-50 and ll.62-63. Specifically, *Hedman* discloses that members 26, 28 include *substantially flat* exterior surfaces 30, 48. Further, *Hedman* teaches that exterior surfaces 30, 48 may be preferably coated with porous material so that bone from respective vertebral body will grow into the porous metal. See col.4, ll.4-9. There is therefore no reason for the exterior or outwardly-facing surfaces of *Hedman* to include a groove. Thus, one skilled in the art, at the time the invention was made, would not modify *Baumgartner* with the teaching in *Hedman* to provide a baseplate with a groove on an outwardly-facing surface. The Examiner is clearly using hindsight reconstruction to find elements in other references and combine them to suggest the limitations of claim 1. Therefore, claim 1 is not rendered obvious by *Baumgartner* in view of *Hedman*. Claims 2-9 are unobvious, *inter alia*, by virtue of their dependence from claim 1, which is unobvious for the reasons set forth above.

Further, the Examiner has rejected claims 11-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent

No. 4,932,969 to *Frey et al.* ("*Frey*") in view of U.S. Patent No. 5,926,685 to *Krebs et al.* ("*Krebs*"). The Examiner asserts that *Frey* discloses an artificial intervertebral disc with first and second baseplates 4 and 5 having dome-shaped outward facing surfaces. *Frey* discloses that the baseplates are formed in multiple layers and according to the Examiner the outward layer of the multiple layers may be considered an outwardly facing surface. The Examiner also asserts that the mesh is fully capable of having a convexity depth or footprint proximate depth of a concave surface in a vertebrae. The Examiner cites *Krebs* for teaching using a coating or a binder to secure a metal mesh to the surface of an implant and further contends it would have been obvious for one skilled the art to use the method as taught by *Krebs* with the implant of *Frey* such that it provides a more secure mesh to the implant surface and eliminates any sliding of the baseplates.

Independent claim 11 includes the limitation that the first and/or second baseplates have an outwardly facing surface. Claim 11 also includes the limitation that a vertebral body contact element is attached to the outwardly facing surface of the respective baseplates. Thus, the present invention has an outwardly facing surface and a vertebral body contact element. Claim 11 has been amended to include the recitation that the central region of the vertebral contact element is remote from the outwardly-facing surface of the first and/or second baseplates so as to form a gap therebetween when the vertebral body contact element is in a relaxed state. In the Examiner's own words, the device in *Frey* discloses multiple layers, and since there are multiple layers the outer layer can be considered a domed mesh or contact element and an inner layer or baseplate. There is no teaching or suggestion in *Frey* that the central region of the vertebral contact element is remote from

the outwardly-facing surface of the first and/or second baseplates so as to form a gap therebetween when the vertebral body contact element is in a relaxed state. Further, *Frey* cannot be combined with *Krebs* to cure this deficiency.

In addition, the multiple layer structure of *Frey* does not disclose baseplates, but rather a pair of anchoring elements 4,5 which are wire meshes anchored in a hollow body 6. The hollow body is sandwiched between the anchoring elements and consists of a compressible plastic. It is unclear to Applicants as to how the part of the anchoring elements 4, 5 may be considered a baseplate, and another part of the anchoring elements 4, 5 may be considered a vertebral body contact element. Applicants respectfully assert that the Examiner is rejecting claim 11 without looking at all of the recitations included within that claim. For these reasons, claim 11 is not rendered obvious by *Frey* in view of *Krebs*. Claims 12-20 are unobvious, *inter alia*, by virtue of their dependence from claim 1, which is unobvious for the reasons set forth above.

Further, the Examiner rejected claims 21-41 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No.5,370,697 to *Baumgartner* ("*Baumgartner*") in view of U.S. Patent No. 5,926,685 to *Krebs et al.* ("*Krebs*"). Amended independent claims 21 and 31 include recitations that are neither taught nor suggested in *Baumgartner* and *Krebs*. As stated above, *Baumgartner* cannot be combined with *Hedman* to provide a baseplate with a groove on an outwardly-facing surface. Further, *Baumgartner* cannot be combined with *Krebs* to cure this deficiency. Therefore, amended claims 21 and 31 are not rendered obvious by *Baumgartner* in view of *Krebs*. Claims 22-30, and 32-41 are unobvious, *inter alia*, by virtue of their dependence from independent claims 21 and 31 respectively, which are unobvious for the reasons set forth above.


As it is believed that all of the objections and rejections set forth in the Office Action have been fully met by the foregoing amendments and remarks, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' agent at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested Amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: April 27, 2007

Respectfully submitted,

By 
William A. Di Bianca
Registration No.: 58,653
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Agent for Applicant

755619_1.DOC